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On: November 1, 2002

By: Leslie Lindsay

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	James W. Schumm et al.	**Docket No.:**	016026.9180
Serial No.:	09/784,423	**Group Art Unit:**	1631
Filed:	February 15, 2001	**Examiner:**	James Martinell
Confirmation No:	5149		

FOR: MATERIALS AND METHODS FOR IDENTIFYING AND ANALYZING INTERMEDIATE TANDEM REPEAT DNA MARKERS

RESPONSE TO OFFICE COMMUNICATION

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

This submission relates to the above-identified patent application, in response to the Office communication mailed October 1, 2002, Applicants reply as follows.

Claims 22-34 are pending in the application. In the Office communication, the Examiner identified two inventions: Group I (claims 22-30), drawn to methods of detecting DNA and kits; and Group II (claims 31-34), drawn to oligonucleotide probes, and required restriction to one invention under 35 U.S.C. §121. Applicants note that claims 22-30 all relate to methods of detecting DNA, and that the kit claims (claims 31 and 32) were listed in the Group II invention. Applicants assume that the Examiner intended that claims 31 and 32 were intended to be included with the Group I claims drawn to methods of detecting DNA and kits. Accordingly, Applicants elect the Group I claims 22-32 with traverse.

Applicants respectfully submit that all claims of the present application could be examined together without placing any serious burden on the United States Patent and Trademark Office. The claims of Groups I and II are so closely related to one another that, for efficiency, they should be examined in a single application. All the claims are either methods for isolating and/or analyzing fragments of DNA containing intermediate tandem

repeats, kits for practicing such methods, or oligonucleotides for use in the methods. A complete search of the prior art for any one of the groups, would require a search of the subject matter of the others.

In addition to requiring restriction to one of the two groups of claims, discussed above, the Examiner stated that the Applicant must select no more than ONE of the individual marker sequences, and no more than ONE PAIR of primers/probes. Applicants believe that this requirement is improper, in view of the fact that independent claims 22, 26, and 31 contain only ten different DNA marker sequences (SEQ ID NO:28, SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:41, SEQ ID NO:42, and SEQ ID NO:43). Because there are only ten such nucleotide sequences in alternative form, they should not be subject to restriction under 35 U.S.C. 121. Claim 30 depends from and further limits claim 26, and specifically recites ten different primer pairs that may be used to amplify the ten different marker sequences recited in claim 26.

The Examiner stated that claims 22-34 are drawn to or mention nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than ten individual, independent and distinct nucleotide sequences in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996). The Official Gazette citation refers to a position paper published by then Commissioner Lehman, which provides guidelines for U.S. Patent and Trademark Office Examiners to use in determining when and how claims containing nucleotide sequences should be restricted. The guidelines has since been incorporated into § 803.04 of the MPEP.

Applicants select the marker identified by SEQ ID NO:32 and the primer pair identified by SEQ NO:124 and SEQ ID NO:125, with traverse. Applicants respectfully submit that restriction to only <u>one</u> of the sequences or one primer pair is improper. The claims recite nucleic acid sequences in the alternative, in a "Markush" type format, with claims 22, 26, and 31 reciting ten marker sequences, and claim 30, which depends from claim 26, recited ten primer pairs, each of which serves as a primer pair to amplify one of the ten marker sequences of claim 26. At a minimum, Applicants should be allowed to select ten sequences to be examined.

The MPEP §803.02 states that:

> "....it is improper for the [patent] office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.
>
> * * * *
>
> ...unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

Applicants respectfully submit that both of the requirements for unity of invention are met by the nucleotides sequences of the claimed invention.

The oligonucleotide pairs identified by SEQ ID NOs: 116 and 117, 124 and 125, 132 and 133, 134 and 135, 136, and 137, 138 and 139, 140 and 141, 142 and 143, 144, and 145, and 146 and 147 share a common utility with the markers of claims 22, 26, and 30 in that they are used in the claimed methods and kits to analyze the markers. The oligonucleotide sequences also share a common structural feature with the marker sequence in that they are complementary to a region of the sequence flanking the region of the DNA marker containing the intermediate tandem repeat sequence. That particular structural feature of the oligonucleotide pairs makes the oligonucleotide primers useful in analyzing the intermediate tandem repeat sequences in marker sequences according to the methods and kits of the present invention.

Because all of the sequences listed in Markush groups in each of claims 22, 26, 27, and 31 share a common utility and a structural feature essential to that utility, Applicants respectfully submit that a unity of invention exists among all the nucleic acid sequences recited in all the claims of the present application. Therefore, Applicants respectfully submit that restriction of examination to only one of the marker sequences and one of the primer pairs listed in the subject claims would be improper, under 35 U.S.C. §121, as interpreted in MPEP § 803.02.

Applicants respectfully submit that it would be improper to require restriction of claims which are not specifically directed to nucleic acids, but which include lists of nucleic acid sequences. Specifically, Applicants submit that the ten sequence limitation set forth in MPEP § 803.04 is clearly directed toward nucleotide sequence composition claims. The examples of claims effected by the sequence limitation, as put forth in the MPEP § 803.04, are all examples of composition claims.

For reasons stated above, Applicants respectfully submit that restriction of examination to one of the two groups of claims set forth in the Office Action would be improper, under 35 U.S.C. §121, as would restriction to no more than one of the marker sequences and one of the primer pairs. In view of the above, Applicants respectfully request reconsideration and withdrawal of both restriction requirements.

Respectfully submitted,

Date: November 1, 2002

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